



PTO/SB/33 (07-05)

Approved for use through xx/xx/200x. OMB 0651-00xx

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays an OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEWDocket Number (Optional)
36731-000093/US

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

Application Number
10/591,321Filed
August 31, 2006First Named Inventor
Morton REESLEV et al.Art Unit
1657Examiner
Paul C. Martin

On _____

Signature _____

Typed or printed name _____

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 35,094.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

John A. Castellano
Typed or printed name(703) 668-8000
Telephone numberMay 13, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Morton REESLEV et al.
Application No.: 10/591,321
Filing Date: August 31, 2006
Conf. No.: 9441
Group Art Unit: 1657
Examiner: Paul C. Martin
Title: Filtration Method for Detecting Microbial Contamination
(*As Amended*)
Atty. Dkt. No.: 36731-000093/US

Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314
Mail Stop **Appeal**

May 13, 2010

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

In response to the "final" Office Action mailed on January 13, 2010 (hereinafter 'Action'), Appellants request that the Pre-Appeal Brief Review Board (hereinafter 'Board') review the pending rejections, concurrently with the filing of a Notice of Appeal.

Claims 1-13, 15-18, 20-30, 34, 37-42, 44, 45 and 48-58 are pending in the current application. Claim 1 is the sole independent claim. No claim amendments are being filed in conjunction with this request.

I. MATERIAL UNDER REVIEW

Review is requested for the rejections of claims 1-13, 15-18, 20-30, 34, 37-42, 44, 45 and 48-58 under 35 U.S.C. §103(a) as being unpatentable over Tuompo et al. (hereinafter 'Tuompo'), U.S. Patent No. 5,714,343 in view of Koumara et al. (hereinafter 'Koumara'), U.S. Patent No. 4,591,554.

Independent claim 1 recites a method of detecting contaminants in a medium suspected of containing such contaminants including (*inter alia*) “c) allowing the substrate to interact with the contaminants on the influent side of the filter in the filter device for a period of time, which is sufficient to allow the detectable moiety to be detected in the liquid vehicle,” “d) evacuating the liquid vehicle from the influent side of the filter by forcing the liquid vehicle through to the effluent side of the filter” and “e) performing a quantitative or qualitative detection of the detectable moiety in the liquid vehicle evacuated in step d and correlating the detection of the moiety to the amount or presence of contaminants in the sample.” Appellants note that the independent claim stands rejected solely under 35 U.S.C. §103(a).

OMISSION OF ESSENTIAL ELEMENTS IN THE §103(a) REJECTION

First, acknowledging the deficiencies of Tuompo with respect to steps d) and e) as recited in independent claim 1, the rejection states that “[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to evacuate (elute) the colored enzymatic reaction product by applying either an elevated pressure on the influent side of the filter or applying a lowered pressure on the effluent side of the filter because one of ordinary skill in the art would have recognized this as an automation of the gravity filtration process taught by Tuompo et al. when using the MTT substrate and the automation of a previously manual activity is *prima facie* obvious (See MPEP, *In re Venner*).”¹

However, Appellants submit that nothing in Tuompo implies that the MTT should be detected in the test solution on the effluent side of the filter. That is, detection could be performed by analysis of the filter or the liquid on the influent side of the filter. Apart from this, Tuompo states that “[i]ndeed, NBT is a preferred chromogenic reagent for use in the invention...”² Also, “NBT and MTT are equally rapid from the point of view of color formation, but the advantage of NBT in comparison with MTT is that the color can be deposited on a restricted area of the filter because it precipitates at the point where the dehydrogenases are situated around the bacteria.”³

Furthermore, in the examples provided in Tuompo, the cells are counted directly on the filter, and small amounts of the test solution including the chromogenic agent are used. Tuompo does not suggest the use of larger volumes of test solution which would be needed in

¹ Action, p. 8.

² Tuompo, col. 3, ll. 9-13.

³ Tuompo, col. 3, ll. 14-18 (emphasis added).

order to perform detection on any test solution that passes through the filter. Thus, even if using NBT, there is no suggestion that NBT is detected in the test solution on the effluent side of the filter. As such, nothing in Tuompo teaches, or suggests, that any of the embodied chromogenic reagents (MTT or NBT) are detected in the test solution on the effluent side of the filter.

Koumura, which is directed to a method for detecting microorganisms, does not use a filter for detection. Furthermore, Koumura teaches that a test solution with a sample solution is mixed, and then the mixed test solution is isolated by centrifugation and subsequently subjected to measurement. For example, see Examples 1 and 2 of Koumura.

If using the larger volumes of test reagent as taught in Koumura, Koumura teaches that centrifugation is used to separate contaminants from the test reagent. If using the smaller volumes as taught by Tuompo, one would inspect the filter directly, as discussed above. Thus, as evidenced by the teachings in the reference, the combination of Tuompo and Koumura does not lead one to perform steps d) and e) as recited in claim 1. Therefore, Koumura fails to remedy the above-noted deficiencies of Tuompo with respect to independent claim 1.

In order to establish a *prima facie* case of obviousness predicated on a combination of documents, the combination must teach, or suggest, all of the claim limitations, cf. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Or, if the documents are missing claimed features, there must be some apparent reason either in the documents or the general knowledge in the art by which to modify the documents to include the missing subject matter in the fashion claimed, cf. *Id.* and *KSR Int'l, Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 82 USPQ2d 1385, 1396 (2007) (obviousness includes determining whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue).

Further, MPEP §2143 states that "...[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious..." which should be made explicit and must be anchored by a rational underpinning, as directed by *KSR Int'l Co. v. Teleflex Inc.*

Neither Tuompo nor Koumura teaches the combined steps of passing the liquid medium through the filter and subsequently determining a "detectable moiety" on the effluent side of the filter. Furthermore, neither the references nor the common general knowledge provides for "an apparent reason" to determine the detectable moiety on the effluent side of the filter.

For at least these reasons, Appellants submit that the §103(a) rejection in view of Tuompo and Koumura fails to teach, or suggest, all of the claim limitations recited in independent claim 1, in particularly, “d) evacuating the liquid vehicle from the influent side of the filter by forcing the liquid vehicle through to the effluent side of the filter” and “e) performing a quantitative or qualitative detection of the detectable moiety in the liquid vehicle evacuated in step d and correlating the detection of the moiety to the amount or presence of contaminants in the sample.” Therefore, the §103(a) rejection omits essential elements necessary to establish a proper *prima facie* case of obviousness.

Secondly, the rejection states that Tuompo et al. teaches a method for the detection of viable microorganisms including “...allowing the chromogenic substrate to interact with the microorganisms (bacteria) for a period of time wherein the interaction is not terminated...”⁴

However, Tuompo teaches that “[a]fter filtration to separate microorganisms in the sample from any free reducing compounds present in the sample, a test solution containing a chromogenic reagent is added and drawn through the filter.”⁵ Thus, there is no teaching in Tuompo that the test solution should remain on the influent side of the filter to allow a reaction to take place before passing the test solution to the effluent side of the filter. That is, Tuompo describes a method, where bacteria are detected on the filter by means of a precipitated chromogenic agent. In Tuompo, it is merely important that the chromogenic agent is brought into contact with the filter surface, where it can precipitate. However, the time interval where the chromogenic agent is present on the influent side of the filter is not essential. Thus, there is no teaching, or suggestion, in Tuompo that the test solution remains on the influent side “for a period of time, which is sufficient to allow the detectable moiety to be detected in the liquid vehicle” as recited in independent claim 1.

Furthermore, Tuompo teaches that it is explicitly preferred that the chromogenic agent should precipitate on the filter and “rapidly” produce a detectable and intensely colored product. On the contrary, Koumura teaches that the reaction product of the chromogenic agent is dissolved. Furthermore, the incubation times in Koumura are twice that of Tuompo to allow the slow-reacting fluorescent agents to react. Thus, Koumura and Tuompo “teach away” from each other in terms of the “period of time” needed to the substrate to interact with the contaminants. In particular, one of ordinary skill in the would not select a

⁴ Action, p. 5.

⁵ Tuompo, col. 2, ll. 53-56.

chromogenic agent (i) that is not precipitated on the filter and (ii) that reacts slowly (as taught by Koumura) for the method taught by Tuompo.

MPEP §2145(X)(D)(2) states that “[i]t is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983) (The claimed catalyst which contained both iron and an alkali metal was not suggested by the combination of a reference which taught the interchangeability of antimony and alkali metal with the same beneficial result, combined with a reference expressly excluding antimony from, and adding iron to, a catalyst.).

For at least these reasons, Appellants submit that the §103(a) rejection fails to consider the nature of the teachings of both Tuompo and Koumura, in particular, the portions of the references that “teach away.” Therefore, the §103(a) rejection omits essential elements necessary to establish a proper *prima facie* case of obviousness.

II. CONCLUSION

In view of the above remarks, Appellants respectfully request that the Board recommend reconsideration and withdrawal of the art ground of rejection and allowance of the pending claims, absent a non-final rejection based on more relevant prior art references.

Should there be any outstanding matters that need to be resolved in the present application, the Board is respectfully requested to contact the undersigned at the telephone number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By

John A. Castellano, Reg. No. 35,094

P.O. Box 8910
Reston, Virginia 20195
(703) 668-8000


JAC/CDW